

# **Exhibit F (part 2)**

influenced the decisions of health care providers submitting Medicare and Medicaid claims . . .

Based on the evidence collected, [your company] should make arrangements to compensate taxpayers for the financial injury caused to federally funded programs. Any refusal to accept responsibility will most certainly be indicative of the need for Congress to control drug prices. If we cannot rely upon drug companies to make honest and truthful representations about their prices, then Congress will be left with no alternative but to take decisive action to protect the public.

October 31, 2000 letter from Hon. Fortney Pete Stark of California to Miles White, Chief Executive Officer, Abbott Laboratories, Abbott Park, Illinois. Congressional Record, October 31, 2000, at E2037-38.

132. The investigation led by Congressman Stark concluded that defendants employed a number of financial inducements to stimulate the sales of their drugs at the expense of both Medicare and Medicaid. Such inducements include the practices described herein, *i.e.*, volume discounts, rebates, off-invoice pricing and free goods designed to lower the net cost to the purchaser while keeping high the cost of the drug to government programs:

Some drug companies have also utilized a large array of other impermissible inducements to stimulate sales of their drugs. These inducements, including bogus "educational grants", volume discounts, rebates or free goods, were designed to result in a lower net cost to the purchaser while concealing the actual cost price beneath a high invoice price. A product invoiced at \$100 for ten units of a drug item might really only cost the purchaser half that amount. Given, for instance, a subsequent shipment of an additional ten units at no charge, or a "grant", "rebate" or "credit memo" in the amount of \$50, the transaction would truly cost a net of only \$5.00 per unit. Through all these "off-invoice" means, drug purchasers were provided the substantial discounts that induced their patronage while maintaining the fiction of a higher invoice price-the price that corresponded to reported AWP's and inflated reimbursement . . .

September 28, 2000 Congressional Record at E1623.

133. Congressman Stark provided numerous examples of the manipulation of AWP, based on documents he had obtained from defendants:

(a) In the 2000 edition of the *RedBook*, defendant Bristol-Myers reported an AWP of \$1,296.64 for one 20 mg/ml, 50 ml vial of Vepesid (Etoposide) for injection, while selling the exact same drug in the same quantity to a group purchasing organization for \$70. This represents a spread between Bristol Myers' falsely inflated AWP and the real price of \$1,226.64. Congressional Record, September 28, 2000 at E1623.

(b) Effective January 10, 1995, defendant Glaxo increased the AWP for Zofran by 8.5 percent while simultaneously giving a 14 percent rebate to providers that more than offset the price increase to Medicaid. The net effect of these adjustments was to increase the amount of reimbursements available to providers from payors whose reimbursement is based on AWP. Because the net price paid to Glaxo for Zofran actually went down, the increase in the AWP did not increase revenue per unit to Glaxo. This adjustment demonstrates an intent to induce providers to purchase Zofran by enabling them to receive increased reimbursement from Medicaid and other third party payors. *Id.* at E1622.

(c) Abbott's Amikacin, used to treat an infection that HIV positive people are susceptible to, had an AWP of \$54.56. The actual best price was \$6.75. Abbott's Vancomycin, an antibiotic used to treat intestinal infections, had an AWP of \$68.77 as of April 2000. DOJ adjusted it to \$8.14. Congressional Record, October 31, 2000 at E2038.

(d) Subpoenaed documents from Fujisawa likewise indicate the companies' fraudulent efforts to manipulate reimbursements. One document between Fujisawa employees reveals the following:

"Many thanks to Rick and Bruce for adjusting the AWP on the five gram Vanco. This should lead to more business . . . I would have

liked to see us match Abbott's AWP for our complete Vanco, and Cefazolin line. I will settle for the five gram at \$1 below Abbott but that means that we will still have to compete at the other end of the equation. For example, if Abbott's AWP is \$163 we will have to be at least \$29 to have the same spread. Follow?"

Stark letter to PhRMA, Congressional Record, September 28, 2000 at E1622.

134. A September 21, 2000 GAO Report determined that actual retail prices for top Medicaid/Medicare drugs, such as Albuterol and Ipratropium bromide, were 85 percent and 75 percent less than their AWPs. Applying this range of percentages to New York City's Medicaid costs, the overcharges add up to millions of dollars annually. GAO, *Payments for Covered Outpatient Drugs Exceed Providers' Cost*, September 2001 (GAO-01-1118) at 4.

135. That same GAO report found that:

Widely available discounts for 17 of the physician-billed drugs we examined averaged between 13 percent and 34 percent less than AWP.

For two other physician-billed drugs, Dolasetron mesylate and Leucovorin calcium, average discounts were considerably larger – 65 percent and 86 percent less than AWP

GAO-01-1118 at 11-12.

136. In 2001, an HHS OIG report estimated that pharmacies' actual acquisition cost for brand name prescription drugs was, at the low end, 21.84% below the reported AWP across the board. The OIG estimated that as much as \$1.08 billion nationwide could have been saved for the 200 most frequently reimbursed drugs in calendar year 1999 if reimbursement had been based on a greater percentage discount off of AWP. HHS OIG, *Medicaid Pharmacy – Actual Cost of Brand Name Prescription Drug Products* (A-06-00-00023) (August 2001), at 3-4.

137. The OIG has recently warned that drug pricing practices in the private sector may have significant effects on Medicaid rebates:

Discounting arrangements are prevalent in the pharmaceutical industry and deserve careful scrutiny particularly because of their potential to implicate the Best Price requirements of the Medicaid Rebate Program. Because the Medicaid Rebate Program in many instances requires that states receive rebates based on the Best Price offered by a pharmaceutical manufacturer to other purchasers, manufacturers have a strong financial incentive to hide *de facto* pricing concessions to other purchasers to avoid passing on the same discounts to the states. Because of the potential direct and substantial effect of such practices on federal health care program expenditures and the interest of some manufacturers in avoiding price concessions that would trigger rebates to the states, any remuneration from a manufacturer to a purchaser, however characterized, should be carefully scrutinized.

OIG, *Compliance Program Guidance for Pharmaceutical Manufacturers*, 68 Fed. Reg. 23,731-35 (May 5, 2003).

138. A March 27, 2001 report entitled *Medicaid Drug Rebates – Sales to Repackagers Excluded From Best Price Determinations* (A-06-00-00056), issued by the HHS OIG studied the rebate issues for the manufacturers of the top 200 Medicaid reimbursed drugs for Fiscal Year (FY) 1999. It found that many manufacturers failed to include in their Best Price calculations submitted to the federal government discounted sales to repackagers, which buy drugs in bulk and then repackage them in smaller quantities for distribution:

7 out of 53 manufacturers excluded sales to 8 repackagers, 3 of which were HMO repackagers. Sales to HMOs are specifically required by statute to be included in a drug manufacturer's best price determination. As a result, Medicaid drug rebates totaling \$80.7 million for FY 1999 were lost because sales to HMOs were excluded from the best price determinations.

*Id.* at 1. The report found that “[i]n some instances the sales to the HMOs were at prices as much as 75 percent below the reported best price.” *Id.* at 4.

139. The report went on to say that this review was a follow up to previous investigations conducted in response to congressional inquiries. Based on a more limited number of drugs and repackagers it was found that that two “repackagers were HMOs

and that they were purchasing drugs significantly below the manufacturers' reported best prices." This limited study found a loss of \$27.8 million in Medicaid rebates for FY 1998. *Id.* at 1.

140. The report "recommended that the Health Care Financing Administration (HCFA) [now CMS] require drug manufacturers who excluded sales to HMOs from their Best Price to repay the lost rebates." *Id.* at cover page. Rep. Henry A. Waxman (D-CA), who requested the report, said "This report shows that drug manufacturers have used drug repackaging to evade paying rebates to Medicaid." *Drug Companies' Repackaging Scheme Costs Taxpayers Over \$100 Million In 1998 And 1999*, April 5, 2001, pg. 1 of 1, available at [http://www.house.gov/reform/min/pdfs/pdf\\_inves/pdf\\_medi\\_drug\\_IG\\_press.pdf](http://www.house.gov/reform/min/pdfs/pdf_inves/pdf_medi_drug_IG_press.pdf).

141. According to a March 25, 2003 report issued by the OIG, five brand-name drug manufacturers were found to have overcharged AIDS Drug Assistance Programs, public hospitals (including the New York City Health and Hospitals Corporation), and other health care providers that participate in the U.S. Public Health Service's 340B program, a program that provides low cost drugs to such providers based on the same Best Price formula as the Medicaid Rebate Statute. The inspector general found that the drug manufacturers failed to include in their calculations of Best Price the price of drugs sold to HMO repackagers, resulting in millions of dollars of excess charges. Specific drug names and manufacturers were not mentioned in the report. *Pharmaceutical Manufacturers Overcharged 340B-Covered Entities*, March 2003 (A-06-01-00060), at 1.

142. A 2004 OIG report likewise found that 340B entities are being overcharged for outpatient drugs given *inter alia*, drug manufacturers' failures to report Best Price. See June 29, 2004 HHS-OIG report, "Appropriateness of 340B Drug Prices." Notably,

that report examined 2002 drug pricing data, the same year as the data included herein. The OIG concluded that in September 2002 alone, 340B entities overpaid in excess of \$41 million for prescription drugs, and that conduct resulting in the improper overcharges was not limited to one or even a few manufacturers.

143. The U.S. Attorney's Office in Pennsylvania is investigating Eli Lilly's marketing practices of certain drugs, including the osteoporosis drug Evista, the anti-depressant Prozac and Lilly's top selling schizophrenia drug Zyprexa, all of which have been purchased by NYC and are included in this complaint.

144. The GAO, HHS OIG, and DOJ investigations of the fraudulent pricing practices undergirding this complaint are further described in the defendant-specific allegations below.

## **VI. ALLEGATIONS PARTICULAR TO NEW YORK CITY AND THE INDIVIDUAL DEFENDANTS**

145. Exhibit A attached hereto shows the City's expenditures during the calendar year 2002 for the drugs at issue herein.

146. Exhibit A also notes which defendant's drugs for which the City seeks relief are also at issue in other proceedings in this MDL.

147. Exhibit B attached hereto shows a preliminary estimate of the percentage and amount of overcharge for nearly 200 of those same drugs during the year 2002, the majority of them brand name drugs, purchased by Medicaid for City residents. As noted above, the overcharges for generic drugs are expected to be even greater.

148. Moreover, these overcharge estimates are understatements because they do not include the impact of defendants' failures to comply with federal and state Medicaid Rebate Statutes. Defendants are statutorily required to pay rebates based on AMP

minus Best Price, or 15.1% of AMP, whichever is greater, and additional rebates based on the extent to which their AMPs exceed an appropriate adjustment based on the consumer price index. 42 U.S.C. §1396r-8(c)(1)(A).

149. Many facts surrounding each individual defendant's discounting and rebate activities are uniquely within that defendant's control, but the City alleges that each defendant herein routinely offers substantial prompt pay and other discounts, chargebacks, rebates and incentives to wholesalers, chain pharmacies, group purchasing organizations, pharmacists and other distributors of its products to create demand for its products, and that each defendant does not account for all of these activities in its calculation of Best Price, AMP or its payment of Medicaid rebates.

150. At all times relevant hereto, each defendant herein controlled and set the reported AWPs for its drugs through communications with the publishers.

151. On information and belief, each defendant has reported false and inflated AWPs or other wholesale price information on which AWPs are based in years prior and subsequent to 2002, resulting in comparable damage to the City for all covered drugs manufactured by it.

152. The following examples are merely illustrative and are not intended to be an exact or exhaustive recitation of all of the unlawful activity engaged in by each defendant. Additional detail is peculiarly within defendant's control pending discovery.

#### A. ABBOTT

153. As set forth in detail in Exhibit A, the City spent over \$19.5 million on Abbott drugs in 2002 alone. The specific drugs paid for by the City and for which the City seeks relief include those set forth set forth in Exhibit A hereto.

154. The City alleges an intentionally false and misleading AWP for each Abbott drug listed on Exhibit A.

155. Exhibit B sets forth the City's preliminary estimate of the extent of its overcharge on those Abbott drugs for which it paid the greatest amount in 2002.

156. As an example, in 2002 alone, New York City spent over \$1.3 million on Abbott's Norvir. The City's most popular dosage of Norvir was the 100 mg capsule. The City estimates it was overcharged at least 32% per 100 mg cap dosage as a result of Abbott's false AWPs. This translates into an average overcharge of at least \$0.63 per dosage. (See Exhibit B).

157. The City spent over \$4.9 million on Abbott's Depakote. The City estimates it was overcharged at least 20% per dosage as a result of Abbott's false AWPs. *Id.*

158. In connection with the wrongful conduct described herein, Abbott has been investigated by at least the United States Department of Justice, the United States Congress, Commonwealth of Massachusetts, the Office of Inspector General of the Department of Health and Human Services, the Attorneys General of California, Florida, Illinois, Ohio, Texas and Wisconsin, and the State of California Department of Justice Bureau of Medi-Cal Fraud and Elder Abuse. The publicly available results of these investigations confirm Abbott's routine practice of reporting false and inflated wholesale pricing information and non-compliance with rebate obligations.

159. In a report published by HHS (the "HHS Report")<sup>6</sup>, the DOJ documented at least 81 instances where the published AWPs for various dosages of 16 drugs manufactured by Abbott were substantially higher than the actual prices listed by wholesalers.

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<sup>6</sup> "An Additional Source of Average Wholesale Price Data In Pricing Drugs and Biologicals Covered by the Medicare Program," PM Rev. AB-00-86 (Sept. 8, 2000).

The chart below sets forth the 16 drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by Abbott in the 2001 *RedBook*.

Drug	Abbott's 2001 <i>RedBook</i> AWP	DOJ Determined Actual AWP	Difference	Percentage Spread
Acetylcysteine	\$ 35.87	\$ 21.90	\$ 13.97	64%
Acyclovir	\$ 1047.38	\$ 349.05	\$ 698.33	200%
Amikacin Sulfate	\$ 995.84	\$ 125.00	\$ 807.84	697%
Calcitriol (Calcijex)	\$ 1,390.66	\$ 1079.00	\$ 311.66	29%
Cimetidine Hydrochloride	\$ 214.34	\$ 35.00	\$ 179.34	512%
Clindamycin Phosphate	\$ 340.52	\$ 75.35	\$ 265.17	352%
Dextrose	\$ 239.97	\$ 3.91	\$ 236.06	6,037%
Dextrose Sodium Chloride	\$ 304.38	\$ 1.93	\$ 302.45	15,671%
Diazepam	\$ 28.50	\$ 2.03	\$ 26.47	1,304%
Furosemide	\$ 74.52	\$ 14.38	\$ 60.14	418%
Gentamicin Sulfate	\$ 64.42	\$ .51	\$ 63.91	12,531%
Heparin Lock Flush	\$ 38.30	\$ 13.60	\$ 24.70	182%
Methylprednisolone Sodium Succinate	\$ 34.08	\$ 2.30	\$ 31.78	1,382%
Sodium Chloride	\$ 670.89	\$ 3.22	\$ 667.67	20,735%
Tobramycin Sulfate	\$ 150.52	\$ 2.94	\$ 147.58	5,020%
Vancomycin Hydrochloride	\$ 382.14	\$ 4.98	\$ 377.16	7,574%

160. In July 2003, Abbott agreed to pay \$622 million in criminal and civil penalties to resolve allegations that its Ross Products Unit defrauded Medicare and Medicaid by failing to report Best Price. In that proceeding, the U.S. Attorney's Office in the Southern District of Illinois probed whether Ross Products Unit failed to include in calculating Best Price that it had used kickbacks to boost sales and defraud government insurers by

discounting or giving away products. Providers thereafter would seek government reimbursements at higher prices.

161. Abbott also was co-venturer with Japan's Takeda Chemical Industries, Ltd. in TAP Pharmaceuticals, which paid \$875 million in a 2001 settlement of allegations that TAP provided free and unreported samples of Lupron, a prostate cancer drug, to physicians with the understanding that they would bill Medicaid and Medicare for reimbursement based on the inflated AWP.

162. Abbott was among the drug companies to which Congressman Stark sent his October 31, 2000 letter, quoted above.

163. Abbott is among the pharmaceutical companies referred to above now under investigation by the House Committee of Energy and Commerce for possible improper pricing practices and failures to comply with Best Price Rebate requirements.

164. Abbott also is the subject of the investigation led by Senators Grassley and Baucus of the Senate Finance Committee regarding whether it is improperly using the Nominal Price Exception to the Best Price reporting requirements.

165. In addition, Abbott has failed to comply with that part of 42 U.S.C. § 1396r-8(c)(2)(A) that requires the payment of an additional rebate to the extent the AMP for Abbott's drugs has outpaced the increases in the CPI. In court documents filed in the action styled, *County of Suffolk v. Abbott Labs, et. al*, Civil Action 01-CV-12257 PBS (MDL No. 1456 D.Mass.), Abbott maintains that by dividing the total rebate dollars a state receives by the number of units for which these rebates were received, one can arrive at an Abbott drug's "true price". See Abbott Laboratories, Inc.'s Separate Memorandum of Law in Support of Motion to Dismiss Suffolk's Amended Complaint at 4; Abbott's Separate Reply in Support

of Motion to Dismiss at 2 in the mater styled *County of Suffolk v. Abbott Labs, et al.*, Civ. Action No. 01-CV-12257-PBS (MDL No. 1456 D.Mass.). If this is correct, Abbott has never paid the additional CPI rebate required by 42 U.S.C. § 1396r-8(c)(2)(A).

**B. ALCON**

166. As set forth in detail at Exhibit A, the City spent over \$ 2.5 million on Alcon drugs in 2002 alone. The specific drugs paid for by the City and for which the City seeks relief include those set forth set forth in Exhibit A hereto.

167. The City alleges an intentionally false and misleading AWP for each drug listed on Exhibit A.

168. Exhibit B sets forth the City's preliminary estimate of the extent of its overcharge on those Alcon drugs for which it paid the greatest amount.

169. As an example, in 2002 alone, the City spent over \$1.8 million on Alcon's Patanol. The City's most popular dosage of Patanol was the 0.1 percent solution. The City estimates it was overcharged at least 14 percent as a result of Alcon's AWPs. This translates into an average overcharge of at least \$7.79 per dosage. (See Exhibit B).

**C. ALLERGAN**

170. As set forth in detail at Exhibit A, the City spent over \$2.1 million on Allergan drugs in 2002 alone. The specific drugs paid for by the City and for which the City seeks relief include those set forth set forth in Exhibit A hereto.

171. The City alleges an intentionally false and misleading AWP for each drug listed on Exhibit A.

172. Exhibit B sets forth the City's preliminary estimate of the extent of its overcharge on those Allergan drugs for which it paid the greatest amount in 2002.

173. As an example, in 2002 alone, the City spent over \$433,000 on Allergan's Lumigan. The City's most popular dosage of Lumigan was SOL. 0.03%. The City estimates it was overcharged at least 11% as a result of Allergan's AWPs. This translates into an average overcharge of at least \$10.29 per dosage. (See Exhibit B).

**D. THE ALPHARMA GROUP**

174. As set forth in detail at Exhibit A, the City spent over \$2.1 million on Alpharma Group (Alpharma and Purepac) drugs in 2002 alone. The specific drugs paid for by the City and for which the City seeks relief include those set forth in Exhibit A hereto.

175. The City alleges an intentionally false and misleading AWP for each drug listed on Exhibit A.

176. Although the Alpharma Group manufactured certain generic or multi-source drugs, the City's payments were still based on AWP pursuant to N.Y. Soc. Serv. L. § 367-a(9).

177. Certain Alpharma Group drugs listed in Exhibit A were reimbursed at certain times based on the FUL (see Exhibit C) but, as alleged herein, even the FUL is based on an intentionally false and inflated AWP.

178. Exhibit B sets forth the City's preliminary estimate of the extent of its overcharge on those Alpharma Group drugs for which it paid the greatest amount in 2002.

179. As an example, in 2002 alone, the City spent over \$611,000 on Alpharma's Ibuprofen. The City's most popular Ibuprofen was the suspension 100/5ml, for which there was no FUL in 2002 (See Exhibit C). The City estimates it was overcharged at least 69% per suspension 100/5ml unit as a result of Alpharma's false AWPs. This translates into an average overcharge of at least \$15.15 per dosage. (See Exhibit B).

180. The City spent over \$540,000 on Purepac's Metformin. The City's most popular dosage was the 500 mg tablet for which there was no FUL in 2002. (See Exhibit C.) The City estimates that it was overcharged at least 10% per dosage as a result of Purepac's false wholesale pricing information. This translates into an average overcharge of at least \$0.32 per dosage.

181. Alpharma is among the companies referred to above now under investigation by the House Committee of Energy and Commerce for possible improper pricing practices and failures to comply with Medicaid Best Price and rebate requirements.

182. In connection with the wrongful conduct described herein, Purepac has been sued by the Massachusetts Attorney General.

#### **E. THE AMGEN GROUP**

183. As set forth in detail at Exhibit A, the City spent over \$8.3 million on Amgen Group (Amgen and Immunex) drugs in 2002 alone. The specific drugs paid for by the City and for which the City seeks relief include those set forth set forth in Exhibit A hereto.

184. The City alleges an intentionally false and misleading AWP for each drug listed on Exhibit A.

185. Exhibit B sets forth the City's preliminary estimate of the extent of its overcharge on those Amgen Group drugs for which it paid the greatest amount.

186. As an example, in 2002 alone, the City spent over \$583,000 on Amgen's Aranesp. The City's most popular dosage of Aranesp was the INJ 200 mcg. The City estimates it was overcharged at least 28% per dosage as a result of Amgen's false AWPs. This translates into an average overcharge of at least \$253.52 per dosage. (See Exhibit B).

187. Amgen admitted in a press release regarding Aranesp that AWP is “the common basis for reimbursement by payors” and “one of the factors used by Medicare to determine payment for drug charges”.

188. As an example, in 2002 alone, the City spent over \$3.1 million on Amgen’s Epojen. The City’s most popular dosage of Epojen was the Vial 40,000 U/ML. The City estimates it was overcharged at least 23% per dosage as a result of Amgen’s false AWPs. This translates into an average overcharge of at least \$114.85 per dosage (*See Exhibit B*).

189. As another example, the City spent over \$1.1 million on Immunex’s Enbrel, the City estimates that it was overcharged at least 26% per dosage as a result of Immunex’s false AWPs. This translates into an average overcharge of at least \$36.15 per dosage. *Id.*

190. Amgen knows its purchasers’ profits depend on reimbursement rates for drugs, and that Amgen’s own sales and profits in turn depend on its customers’ reimbursement payments and profits:

Our sales depend on payment and reimbursement from third-party payors, and a reduction in the payment rate or reimbursement rate could result in decreased sales of our products.

In both domestic and foreign markets, sales of our products are dependent, in part, on the availability of reimbursement from third-party payors . . . we believe that sales of Aranesp and Neulasta are and will be affected by government and private payor reimbursement policies. . . . If reimbursement for our marketed products changes adversely or if we fail to obtain adequate reimbursement for our other current or future products, health care providers may limit how much or under what circumstances they will administer them, which could reduce the use of our products or cause us to reduce the price of our products. This could result in lower product sales or revenues . . . (Amgen 2002 Form 10-K at 43-44).

191. The Amgen Group admits that it reports AWPs for each of its drugs to the publishers. See Amgen's Answer to the Second Amended Complaint filed in *In re Pharmaceutical Industry Average Wholesale Price Litigation*, Civil Action 01-CV-12257-PBS (MDL No. 1456 D. Mass.) at p.10, ¶ 160.

192. A 1993 OIG Report detailed how Amgen gave substantial year-end rebates to its customers based on their purchases of Epopen, one of the drugs at issue here. The report noted that Medicare and Medicaid beneficiaries did not receive the benefit of any rebates.

193. Thus, at all times relevant hereto, the Amgen Group has known that it can incentivize pharmacies and PBMs to select its drugs by providing substantial discounts while at the same time maintaining a false AWP.

194. In connection with the wrongful conduct described herein, the Amgen Group has been investigated by the United States Department of Justice, the Office of Inspector General of the Department of Health and Human Services and the Attorneys General of the States of Pennsylvania and Wisconsin.

195. Amgen also is the subject of the investigation referred to above led by Senators Grassley and Baucus of the Senate Finance Committee regarding whether it is improperly using the Nominal Price Exception to the Best Price reporting requirements.

#### F. ANDRX

196. As set forth in detail at Exhibit A, the City spent over \$1.8 million on Andrx drugs in 2002 alone. The specific drugs paid for by the City and for which the City seeks relief include those set forth set forth in Exhibit A hereto.

197. The City alleges an allegedly intentionally false and misleading AWP for each drug listed on Exhibit A.

198. Although Andrx manufactured certain generic or multi-source drugs, the City's payments were still based on AWP pursuant to N.Y. Soc. Serv. L. § 367-a(9).

199. Certain Andrx drugs listed in Exhibit A were reimbursed at certain times based on the FUL (*see Exhibit C*) but, as alleged herein, even the FUL is based on an intentionally false and inflated AWP.

200. Exhibit B sets forth the City's preliminary estimate of the extent of its overcharge on those Andrx drugs for which it paid the greatest amount in 2002.

201. As an example, in 2002 alone, the City spent \$786,577 on Andrx's Cartia XT, for which there was no FUL. (*See Exhibit C*). The City's most popular dosage of Cartia XT was the 240/24hr. The City estimates it was overcharged at least 51%, or 94 cents, per 240/24hr dosage as a result of Andrx's false AWPs. (*See Exhibit B*).

#### G. ASTRAZENECA

202. As set forth in detail at Exhibit A, the City spent over \$29 million on AstraZeneca drugs in 2002 alone. The specific drugs paid for by the City and for which the City seeks relief includes those set forth set forth in Exhibit A hereto.

203. The City alleges an intentionally false and misleading AWP for each drug listed on Exhibit A.

204. Exhibit B sets forth the City's preliminary estimate of the extent of its overcharge on those AstraZeneca drugs for which it paid the greatest amount in 2002.

205. As an example, in 2002 alone, the City spent over \$9.1 million on the AstraZeneca's Prilosec. The City's most popular dosage of Prilosec was the 20 mg capsule. Based on its own investigation, described above, the City estimates it was overcharged at least 28% per 20 mg dosage as a result of the AstraZeneca's false AWPs. This translates into an average overcharge of at least \$1.10 per dosage. (*See Exhibit B*).

206. In connection with the wrongful conduct described herein AstraZeneca has been investigated by at least the United States Congress, the Department of Justice, the Office of the Inspector General of the U.S. Department of Health and Human Services and the U.S. Food and Drug Administration.

207. In January 2002, a federal grand jury in Wilmington, Delaware returned an indictment accusing a New Jersey doctor of conspiring with AstraZeneca to resell free samples of Zoladex®, a drug at issue here, that an AstraZeneca sales representatives had given the doctor. The indictment alleged that AstraZeneca (i) sold Zoladex® to the New Jersey doctor and others at prices substantially below the AWP reported by AstraZeneca, and (ii) provided the New Jersey doctor with materials showing how much more profit he could make by using Zoladex® instead of its competitor, Lupron®.

208. In June 2003, AstraZeneca pled guilty and paid \$291 million to settle the Zoladex® charges. The U.S. Food and Drug Administration said in its statement regarding the settlement, “AstraZeneca provided thousands of free samples of Zoladex® to physicians knowing that they would charge their patients and insurance programs for the samples.”

209. On May 29, 2003, AstraZeneca entered into a Corporate Integrity Agreement (“CIA”) with the OIG of the United States Department of Health and Human Services “to promote compliance” “with the statutes, regulations and written directives of Medicare, Medicaid and all other federal health care programs (as defined in 42 U.S.C. 1320a-7b(f))” (“Federal Health Care Program Requirements”). Contemporaneously, AstraZeneca entered into a Settlement Agreement with the United States and various states.

210. The CIA covers any individuals who sell or market government reimbursed products on behalf of AstraZeneca; calculate or report prices; and/or include, negotiate, implement or report information related to government contracts relating to federal health care programs, including Medicare and the Medicaid Drug Rebate program (codified at 42 U.S.C. § 1396r-8 et seq.) The CIA also covers any AstraZeneca employee or agent responsible for "(1) sales and marketing activities for Government Reimbursed Products; (2) the calculation and reporting of prices for federal health care programs, including . . . Medicaid or (3) the negotiation, implementation, and any reporting of information related to government contracts."

211. In addition to promising compliance with federal health care program requirements, the CIA requires AstraZeneca to establish a written code of conduct to be agreed to by each covered person that confirms AstraZeneca's "commitment to full compliance with all federal health care program requirements, including its commitment to comply with all government contracting requirements and to market and sell its government reimbursed products in accordance with federal health care program requirements."

212. The CIA requires further that AstraZeneca implement policies and procedures that address:

- (a) the code of conduct described above as well as;
- (b) the calculation and reporting of accurate prices for Government Reimbursed Products to certain entities, including CMS, the State Medicaid programs, and the drug price reporting services on which government agencies now rely (First DataBank Inc., the *RedBook*, etc.) or shall rely in the future;

(c) the proper calculation and reporting of all data and information reported to CMS and/or the State Medicaid programs in connection with the Medicaid Drug Rebate program, codified at 42. U.S.C. § 1396r-8;

(d) the proper uses and tracking of drug samples in accordance with all applicable requirements, including, but not limited to, the Prescription Drug Marketing Act, codified in 21 U.S.C. §§ 331, 333 and 352; and

(e) measures designed to promote marketing and sales practices that conform with all statutes, regulations and requirements applicable to Government Reimbursed Products. The Policies and Procedures shall specify that AstraZeneca shall comply with the Federal anti-kickback statute, codified at 42 U.S.C. § 1320a-7b(1) & (2), and other applicable statutes, regulations or requirements.

213. The CIA contemplates monetary penalties for non-compliance, and the retention of an independent review organization, ("IRO"). The IRO shall perform two types of review: (1) a systems review of AstraZeneca's systems, processes, policies and practices relating to the Medicaid Drug Rebate Program ("Medicaid Rebate Systems Review") and (2) a review of specific contract price transactions to determine whether those transactions were considered for purposes of determining Best Price in accordance with AstraZeneca's policies and procedures and Medicaid Drug Rebate Program requirements.

214. The publicly available results of these investigations and terms of the CIA confirm AstraZeneca's routine practice of reporting false and inflated wholesale price information and non-compliance with rebate obligations.

215. AstraZeneca now is the subject of an investigation referred to above led by Senators Grassley and Baucus of the Senate Finance Committee regarding whether it is abusing the Nominal Price Exception to the Best Price reporting requirements.

#### **H. THE AVENTIS GROUP**

216. As set forth in detail at Exhibit A, the City spent over \$10.4 million on Aventis Group (Aventis Pharm and Dermik) drugs in 2002 alone. The specific drugs paid for by the City and for which the City seeks relief are set forth set forth in Exhibit A hereto.

217. The City alleges an intentionally false and misleading AWP for each drug listed on Exhibit A.

218. Exhibit B sets forth the City's preliminary estimate of the extent of its overcharge on those Aventis Group drugs for which it paid the greatest amount in 2002.

219. As an example, in 2002 alone, the City spent over \$1.4 million on Aventis Pharm's Allegra. The City's most popular dosage of Allegra was the 180 mg tablet. The City estimates it was overcharged at least 24% per 180 mg dosage as a result of the Aventis Pharm's false AWPs. This translates into an average overcharge of at least \$0.49 per dosage. (See Exhibit B).

220. The City spent over \$2.1 million on Dermik's Penlac Solutions 8%. The City estimates it was overcharged at least 16% per dosage. This translates into an average overcharge of at least \$17.66 per dosage. *Id.*

221. In a report published by the DHHS (AB-00-86), the DOJ documented at least 15 instances where the published AWPs for various dosages of 4 drugs manufactured by Aventis Group were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the 4 drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's

determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by Aventis in the 2001 *RedBook*.

Drug	2001 <i>RedBook</i> AWP	DOJ Determined Actual AWP	Difference	Percentage Spread
Anzemet Injectable (dolasetron Mesylate)	\$ 166.50	\$ 74.08	\$ 92.42	125%
Factor VIII/ Bioclate	\$ 1.25	\$ .91	\$ .34	37%
Factor VIII/ Helixate	\$ 1.18	\$ .78	\$ .40	51%
Gammaglobulin (immune globulin)	\$ 400.00	\$ 296.67	\$ 103.33	35%

222. An OIG report (See "Medicare Reimbursement of Prescription Drugs," OEL-03-00-00310, Jan. 2001) further revealed that: (i) that AWP for all immune globulin 5 mg doses listed in the 1997 *RedBook* were inflated by an average spread of 32.21%; (ii) a 10 mg dose of Anzemet had a Medicare Median of \$14.82 and a Catalog Median of \$8.29, resulting in a spread of 78%; and (iii) a 20 mg dose of Taxotere had a Medicare Median of \$283.65 and a Catalog Median of \$8.29, resulting in a spread of 18.75%. (P006398-006424).

223. In connection with the wrongful conduct described herein Aventis Group has been investigated by at least the United States Department of Justice, the United States Congress, the Office of Inspector General of the Department of Health and Human Services, the Attorneys General for the states of California, Florida, Illinois, Montana, Pennsylvania, Texas and Wisconsin and the State of California Department of Justice Bureau of Medi-Cal Fraud and Elder Abuse. The publicly available results of these investigations confirm the Aventis Group's routine practice of reporting false and inflated wholesale pricing information and non-compliance with rebate obligations.

224. Aventis Pharm is among the pharmaceutical companies referred to above now under investigation by the House Committee of Energy and Commerce for possible improper pricing practices and failures to comply with Best Price Rebate requirements.

225. Aventis Pharm also is the subject of the investigation referred to above led by Senators Grassley and Baucus of the Senate Finance Committee regarding whether it is abusing the Nominal Price Exception to the Best Price reporting requirements.

## I. BARR

226. As set forth in detail at Exhibit A, the City spent over \$2.3 million on Barr drugs in 2002 alone. The specific drugs paid for by the City and for which the City seeks relief include those set forth set forth in Exhibit A hereto.

227. The City alleges an intentionally false and misleading AWP for each drug listed on Exhibit A.

228. Although Barr manufactured certain generic or multi-source drugs, the City's payments were at all times based on AWP pursuant to N.Y. Soc. Serv. L. § 367-a(9).

229. Certain Barr drugs listed in Exhibit A were reimbursed at certain times based on the FUL (*See Exhibit C*) but, as alleged herein, even the FUL is based on an intentionally false and inflated AWP.

230. Exhibit B sets forth the City's preliminary estimate of the extent of its overcharge on those Barr drugs for which it paid the greatest amount in 2002.

231. As an example, in 2002 alone, the City spent over \$713,000 on Barr's Tamoxifen, for which there was no FUL. (*See Exhibit C*) The City's most popular dosage of Tamoxifen was the 20 mg tablet. The City estimates it was overcharged at least 83% per 20 mg dosage as a result of Barr's false AWPs. This translates into an average overcharge of at least \$2.96 per dosage. (*See Exhibit B*).

232. In connection with the wrongful conduct described herein, Barr has been sued by the Commonwealth of Massachusetts Office of the Attorney General. Prior to filing suit the Massachusetts AG had issued a subpoena to Barr for documents related to pricing and Medicaid reimbursement of select products in Massachusetts.

233. Barr also is among the pharmaceutical companies referred to above now under investigation by the House Committee of Energy and Commerce for possible improper pricing practices and failures to comply with Best Price Rebate requirements.

**J. BAYER**

234. As set forth in detail at Exhibit A, the City spent over \$3.1 million on Bayer drugs in 2002 alone. The specific drugs paid for by the City and for which the City seeks relief includes those set forth set forth in Exhibit A hereto.

235. The City alleges an intentionally false and misleading AWP for each drug listed on Exhibit A.

236. Exhibit B sets forth the City's preliminary estimate of the extent of its overcharge on those Bayer drugs for which it paid the greatest amount in 2002.

237. As an example, in 2002 alone, the City spent over \$2.6 million on Bayer's Cipro. The City's most popular dosage of Cipro was the 500 mg tablet. The City estimates it was overcharged at least 16% per 500 mg dosage as a result of Bayer's false AWPs. This translates into an average overcharge of at least \$0.72 per dosage. (See Exhibit B).

238. Bayer's wrongful conduct concerning AWP manipulation and Best Price fraud is not speculative. In connection with the wrongful conduct described herein, Bayer has been investigated by at least the United States Department of Justice, the United

States Congress, the Commonwealth of Massachusetts, and the Office of Inspector General of the Department of Health and Human Services.

239. In January 2002, Bayer agreed to pay a total of \$14 million to the United States and 45 states to settle allegations under the federal False Claims Act that the company caused physicians and other health care providers to submit fraudulently inflated reimbursement claims to state and federally funded Medicaid program. Bayer reached the agreement with the Justice Department, the United States Attorney's Office for the Southern District of Florida in Miami, the Office of Inspector General for the Department of Health and Human Services, and a team of state negotiators from Maine, Nevada, New York and Washington representing the National Association of Medicaid Fraud Control Units.

240. The government's investigation of the allegations, contained in a *qui tam* or whistleblower lawsuit in which the government intervened against Bayer, revealed that, beginning in the early 1990's, Bayer falsely inflated the reported drug prices referred to by the industry as the Average Wholesale Price (AWP), the Direct Price, and the Wholesale Acquisition Cost used by State Governments to set the reimbursement rate for the Medicaid program. According to the DOJ's January 23, 2001 press release, by setting an extremely high AWP, and subsequently selling the product to doctors at a dramatic discount, Bayer induced physicians to purchase its products rather than those of competitors by enabling doctors to profit from reimbursement paid to the by the government. The Bayer AWPs at issue in this settlement were Kogenate, Koate-HP, Gamimmune, which are widely used in treating hemophilia and immune deficiency diseases.

241. The Bayer investigation revealed that the practice in which Bayer selectively engaged, commonly referred to by drug manufacturers as "marketing the spread,"

also had the effect of discouraging market competition from manufacturers that do not inflate AWPs as a way of inducing doctors to purchase their products. In addition to entering into the monetary settlement, Bayer reached a five year agreement with the OIG of HHS that the company's conduct will be monitored by the government under a corporate integrity agreement. Under the compliance agreement, Bayer will provide the state and federal governments with the average selling prices of its drugs in order to facilitate the government's setting of fair reimbursement rates for the company's products, and potentially, the products of any competitors attempting to take advantage of Bayer's cooperation.

242. This Bayer settlement also included settlement of allegations that Bayer knowingly underpaid the Medicaid program for rebates owed by it to the states.

243. In April 2003, Bayer settled certain charges in connection with its efforts to evade paying rebates to states' Medicaid programs which were based on the lowest drug prices they were paying to an HMO, Kaiser Permanente, for Cipro and another Bayer drug, Adalat CC. Bayer is to pay a total of \$275 million to resolve criminal charges and civil liabilities in connection with the fraudulent drug pricing of Cipro and Adalat. The criminal portion of the global agreement calls for Bayer to plead guilty to charges that it violated the Food, Drug and Cosmetic Act by failing to notify the FDA between August and December 1995, of its production of private label Cipro for Kaiser. Bayer has agreed to pay a criminal fine of \$5.6 million and will admit that it engaged in this conduct with the intent to defraud or mislead. In the civil portion of its global settlement, Bayer resolved its federal civil False Claims Act liabilities and pay the United States, 49 states, the District of Columbia, and Public Health Service Entities \$251 million in civil damages for losses suffered by the Medicaid

program and the Public Health Service entities due to Bayer's failure to report its Kaiser private label price to the government as the true Best Price for its drugs.

244. The foregoing settlement implicates none of the City's AWP claims. To the extent it concerned Bayer's Best Price failures, at most, it may have some impact on two years' worth of rebate related damages.

#### **K. BIOVAIL**

245. As set forth in detail at Exhibit A, the City spent over \$1.5 million on Biovail drugs in 2002 alone. The specific drugs paid for by the City and for which the City seeks relief include those set forth set forth in Exhibit A hereto.

246. The City alleges an intentionally false and misleading AWP for each Biovail drug listed on Exhibit A.

247. Exhibit B sets forth the City's preliminary estimate of the extent of its overcharge on those Biovail drugs for which it paid the greatest amount in 2002.

248. As an example, in 2002 alone, the City spent over \$503,000 on Biovail's Cardizem. The City's most popular dosage of Cardizem was the CD Capsule 360 mg/24. The City estimates it was overcharged at least 22% per CD Capsule 360 mg/24 dosage as a result of Biovail's false AWPs. This translates into an average overcharge of at least \$0.64 per dosage. (See Exhibit B).

249. Biovail's practices with respect to Cardizem have been investigated by the U.S. Attorney, District of Massachusetts, and the Office of the Inspector General ("OIG") of Health and Human Services. Specifically, In August 2003, Biovail Corporation announced that it has received notification that the U.S. Office of the Inspector General (OIG) of Health and Human Services has initiated a preliminary administrative inquiry into the Company's clinical experience and marketing programs related to Cardizem L.A. Biovail is

facing an investigation by the HHS Office of Inspector General (OIG) over whether payments to physicians for participating in a survey about its new blood pressure drug were a financial inducement to prescribe the drug.<sup>7</sup>

#### **L. BOEHRINGER GROUP**

250. As set forth in detail at Exhibit A, the City spent over \$5.1 million on Boehringer Group (Boehringer, Boehringer Pharm, Ben Venue, and Roxane) drugs in 2002 alone. The specific drugs paid for by the City and for which the City seeks relief include those set forth set forth in Exhibit A hereto.

251. The City alleges an intentionally false and misleading AWP for each Boehringer Group drug listed on Exhibit A

252. Although the Boehringer Group manufactured certain generic or multi-source drugs, the City's payments were at all times based on AWP pursuant to N.Y. Soc. Serv. L. § 367-a(9).

253. Certain Boehringer Group drugs listed in Exhibit A were reimbursed at certain times based on the FUL (*See Exhibit C*) but, as alleged herein, even the FUL is based on an intentionally false and inflated AWP.

254. Exhibit B sets forth the City's preliminary estimate of the extent of its overcharge on those Boehringer Group drugs for which it paid the greatest amount in 2002.

255. As an example, in 2002 alone, the City spent over \$2.3 million on Boehringer Pharm's Viramune. The City's most popular dosage of Viramune was the 200 mg tablet. Based on its own investigation, described above, the City estimates it was overcharged

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<sup>7</sup> Biovail's misconduct is not confined to Cardizem and fraudulent AWPs. In June 2002, the Federal Trade Commission ("FTC") settled charges that Biovail illegally acquired an exclusive patent license and wrongfully listed that patent in the Orange Book for the purpose of blocking generic competition to its brand-name drug Tiazac. And, in August 2002, the FTC issued a consent order against Biovail and Elan Corporation PLC to resolve charges that they had entered into an agreement that unreasonably reduced competition in the market for the generic anti-hypertension drug, Adalat.

at least 23% per 200 mg dosage as a result of Boehringer Pharm's false AWPs. This translates into an average overcharge of at least \$1.14 per dosage. (See Exhibit B).

256. The City spent over \$113,000 on Roxane's Azathioprine. The City's most popular dosage of Azathioprine was the 50 mg tablet. The City estimates it was overcharged at least 58% per 50 mg dosage as a result of Roxane's false AWPs. This translates into an average overcharge of at least \$0.69 per dosage. (See Exhibit B).

257. In connection with the wrongful conduct described herein, the Boehringer Group has been investigated by the Department of Justice, the Department of Health and Human Services Office of Inspector General, the Committee on Commerce of the House of Representatives, and the Attorneys General for the States of Nevada, Pennsylvania and Wisconsin. The publicly available results of these investigations confirm the Boehringer Group's routine practice of reporting false and inflated wholesale pricing information and non-compliance with rebate obligations.

258. For example, in a report published by HHS, the DOJ documented at least 32 instances where the published AWPs for various dosages of nine drugs manufactured by The Boehringer Group were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the nine drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by The Boehringer Group in the 2001 *RedBook*.

Drug	The Boehringer Group's 2001 <i>RedBook</i> AWP	DOJ Determined Actual AWP	Difference	Percentage Spread
Acyclovir Sodium	\$ 528.00	\$ 207.00	\$ 321.00	155%
Amikacin Sulfate	\$ 437.50	\$ 65.53	\$ 372.17	570%

Mitomicyn	\$ 128.05	\$ 51.83	\$ 76.22	147%
Cytarabine	\$ 62.50	\$ 3.55	\$ 58.95	1,661%
Doxorubicin HCL	\$ 945.98	\$ 139.75	\$ 806.23	577%
Etoposide	\$ 110.00	\$ 8.45	\$ 101.55	1,202%
Leucovorin Calcium	\$ 184.40	\$ 2.76	\$ 181.64	6,581%
Methotrexate Sodium	\$ 68.80	\$ 2.63	\$ 66.17	2,516%
Vinblastine Sulfate	\$ 212.50	\$ 8.19	\$ 204.31	2,495%

259. Boehringer Group's Roxane is among the pharmaceutical companies referred to above now under investigation by the House Committee of Energy and Commerce for possible improper pricing practices and failures to comply with Best Price Rebate requirements.

260. Boehringer also is the subject of the investigation referred to above led by Senators Grassley and Baucus of the Senate Finance Committee regarding whether it is abusing the Nominal Price Exception to the Best Price reporting requirements.

#### **M. THE BMS GROUP**

261. As set forth in detail at Exhibit A, the City spent over \$36.3 million on the BMS Group (Bristol-Myers, Westwood and OTN and collectively referred to as "BMS") drugs in 2002 alone. The specific drugs paid for by the City and for which the City seeks relief include those set forth set forth in Exhibit A hereto.

262. The City alleges an intentionally false and misleading AWP for each BMS drug listed on Exhibit A

263. Although BMS Group manufactured certain generic or multi-source drugs, the City's payments were at all times based on AWP pursuant to N.Y. Soc. Serv. L. § 367-a(9).

264. Certain BMS Group drugs listed in Exhibit A were reimbursed at certain times based on the FUL (*See Exhibit C*) but, as alleged herein, even the FUL is based on an intentionally false and inflated AWP.

265. Exhibit B sets forth the City's preliminary estimate of the extent of its overcharge on those BMS drugs for which it paid the greatest amount in 2002.

266. As an example, in 2002 alone, the City spent over \$3.1 million on Bristol-Myers' Glucophage. The City's most popular dosage of Glucophage was the 500 mg tablet. The City estimates it was overcharged at least 12% per dosage as a result of the BMS Group's false AWPs. This translates into an average overcharge of at least \$0.07. (*See Exhibit B*).

267. The City spent over \$1.6 million on Westwood's Lac-Hydrin. The City's most popular dosage was the LOT 12% 400 gm. Based on its own investigation, the City estimates it was overcharged at least 25% per dosage as a result of Bristol-Myers' or Westwood's false AWPs. This translates into an average overcharge of at least \$14.45.

268. In connection with it's the wrongful conduct described herein, Bristol-Myers has been investigated by the United California Department of Justice Office of the Attorney General, State of California Department of Justice, Bureau of Medi-Cal Fraud and Elder Abuse, and the U.S. House of Representatives Committee on Commerce, and the Attorneys General of the States of Florida, Pennsylvania, Texas and Wisconsin. The publicly available results of these investigations confirm the Boehringer Group's routine practice of reporting false and inflated wholesale price information and non-compliance with rebate obligations.

269. For example, by letter dated February 27, 2001 to Bristol-Myers, Representative Stark outlined numerous examples of specific illegal practices by Bristol-Myers. Referring to a letter from Denis Kaszuba, a senior pricing analyst at Bristol-Myers to Medispan dated August 10, 1992, Rep. Stark noted:

Bristol has control over the AWPs, DPs, and WACs published for its drugs and directs national publishers to change their prices. Bristol directed a national publisher of drug prices to increase all of Bristol's AWPs for oncology drugs by multiplying Bristol's supplied direct prices by a 25% factor rather than the previous 20.5% factor . . . Increasing the AWP created a spread that, in itself, provided a financial kickback to oncologists for prescribing Bristol's cancer drugs.

270. In the same letter, Rep. Stark noted:

The evidence clearly shows that Bristol has intentionally reported inflated prices and has engaged in other improper business practices in order to cause its customers to receive windfall profits from Medicare and Medicaid when submitting claims for certain drugs. The evidence further reveals that Bristol manipulated prices for the express purpose of expanding sales and increasing market share of certain drugs where the arranging of a financial benefit or inducement would influence the decisions of healthcare providers submitting the Medicare and Medicaid claims.

271. Bristol-Myers is among the pharmaceutical companies referred to above now under investigation by the House Committee of Energy and Commerce for possible improper pricing practices and failures to comply with Best Price Rebate requirements.

272. Bristol-Myers also is the subject of the investigation referred to above led by Senators Grassley and Baucus of the Senate Finance Committee regarding whether it is abusing the Nominal Price Exception to the Best Price reporting requirements.

#### N. DEY

273. The specific drugs paid for by the City and for which the City seeks relief include those set forth set forth in Exhibit A hereto.

274. The City alleges an intentionally false and misleading AWP for each Dey drug listed in Exhibit A.

275. Although Dey manufactured certain generic or multi-source drugs, the City's payments were at all times based on AWP pursuant to N.Y. Soc. Serv. L. § 367-a(9).

276. Certain Dey drugs listed in Exhibit A were reimbursed at certain times based on the FUL (*See Exhibit C*) but, as alleged herein, even the FUL is based on an intentionally false and inflated AWP.

277. Exhibit B sets forth the City's preliminary estimate of the extent of its overcharge on those Dey drugs for which it paid the greatest amount in 2002.

278. As an example, in 2002 alone, the City spent over \$370,000 on Dey's Albuterol. One of the more popular dosages was Albuterol 90% mcg aerosol, for which there was no FUL in 2002. The City estimates it was overcharged at least 56% per dosage of the 90 mcg aerosol as a result of Dey's false AWPs. This translates into an average overcharge of at least \$10.86 per dosage. (*See Exhibit B*).

279. In connection with the wrongful conduct described herein, Dey has been investigated by the United States Department of Justice, United States Department of Health and Human Services, Office of Inspector General, the United States District Attorney for the District of Massachusetts, and the Attorneys General for the States of California, Minnesota, Montana, Ohio, Pennsylvania, Texas, West Virginia and Wisconsin.

280. The Texas case concerned two of the Dey drugs at issue here, albuterol sulfate and ipratropium bromide. The Texas AG alleged that between 1995-1999 Dey defrauded the Texas State Medicaid program by reporting false wholesale pricing data for these drugs. In June 2003, Dey settled the Texas allegations for \$18,500,000.

281. The publicly available results of these investigations confirm Dey's routine practice of reporting false and inflated AWPs and non-compliance with rebate obligations.

282. For example, in its own suit against Dey and other pharmaceutical manufacturers for AWP manipulation, the Attorney General for the State of Connecticut documented significant spreads between Dey's published AWPs and actual wholesale prices for many of its drugs. Incorporated below are examples cited by the Connecticut Attorney General:

Drug	NDC#	Year	AWP	ACTUAL PRICE	SPREAD	% OVERCHARGE
ALBUTEROL	49502-0303-17	1996	\$21.70	\$3.25	\$18.45	488%
IPATROPIUM BORMIDE	49502-0685-03	2001	\$44.10	\$8.35	\$35.58	355%
IPATROPIUM BORMIDE	49502-0685-03	2000	\$44.10	\$11.45	\$32.65	239%
IPATROPIUM BORMIDE	49502-0685-03	1999	\$44.10	\$11.45	\$30.11	177%

283. In a report published by HHS, the DOJ documented at least 15 instances where the published AWPs for various dosages of 4 drugs manufactured by Dey were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the drugs identified by the DOJ and the spread associated with one particular dosage of each of the 4 drugs. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by Dey in the 2001 *RedBook*.

Drug in Lowest Dosage Form	2001 <i>RedBook</i> AWP	DOJ Determined AWP	Difference	Percentage Spread
Acetylcysteine	\$59.88	\$25.80	\$34.08	132%
Albuterol Sulfate	\$30.25	\$9.17	\$21.08	230%
Cromolyn Sodium	\$42.00	\$23.01	\$18.99	82%
Metaproterenol Sulfate	\$30.75	\$11.29	\$19.46	172%

284. Dey is among the pharmaceutical companies referred to above now under investigation by the House Committee of Energy and Commerce for possible improper pricing practices and failures to comply with Best Price Rebate requirements.

**O. EISAI**

285. As set forth in detail at Exhibit A, the City spent over \$2 million on Eisai drugs in 2002 alone. The specific drugs paid for by the City and for which the City seeks relief are set forth set forth in Exhibit A hereto.

286. The City alleges an intentionally false and misleading AWP for each Eisai drug listed in Exhibit A.

287. Although Eisai manufactured certain generic or multi-source drugs, the City's payments were at all times based on AWP pursuant to N.Y. Soc. Serv. L. § 367-a(9).

288. Certain Eisai drugs listed in Exhibit A were reimbursed at certain times based on the FUL (See Exhibit C) but, as alleged herein, even the FUL is based on an intentionally false and inflated AWP.

289. Exhibit B sets forth the City's preliminary estimate of the extent of its overcharge on those Eisai drugs for which it paid the greatest amount in 2002.

290. As an example, in 2002 alone, the City spent over \$2 million on Eisai's Aricept. The City's most popular dosage of Aricept was the 10 mg tablet, for which there was no FUL in 2002. The City estimates it was overcharged at least 24% per 10 mg dosage as a result of Eisai's false AWPs. This translates into an average overcharge of at least \$1.02 per dosage. (See Exhibit B).

291. Eisai also is the subject of an investigation referred to above led by Senators Grassley and Baucus of the Senate Finance Committee regarding whether it is abusing the Nominal Price Exception to the Best Price reporting requirements.

P. ELI LILLY

292. As set forth in detail at Exhibit A, the City spent over \$33 million on Eli Lilly drugs in 2002 alone. The specific drugs paid for by the City and for which the City seeks relief include those set forth set forth in Exhibit A hereto.

293. The City alleges an intentionally false and misleading AWP for each drug listed on Exhibit A.

294. Exhibit B sets forth the City's preliminary estimate of the extent of its overcharge on those Eli Lilly drugs for which it paid the greatest amount in 2002.

295. As an example, in 2002 alone, the City spent \$2.6 million on Eli Lilly's Humulin. The City's most popular dosage of Humulin was the Vial 100 u/ml. The City estimates it was overcharged at least 23% per Vial u/ml dosage as a result of Eli Lilly's false AWPs. This translates into an average overcharge of at least \$5.43 per dosage. (See Exhibit B).

296. Eli Lilly is among the pharmaceutical companies referred to above now under investigation by the House Committee of Energy and Commerce for possible improper pricing practices and failures to comply with Best Price Rebate requirements.

297. Eli Lilly also is the subject of the investigation referred to above led by Senators Grassley and Baucus of the Senate Finance Committee regarding whether it is abusing the Nominal Price Exception to the Best Price reporting requirements.

298. Eli Lilly's unlawful efforts to create market share also include allegedly fraudulent marketing practices. The U.S. Attorney's Office in Pennsylvania is investigating Eli Lilly's marketing practices of certain drugs, including Evista, Prozac and Zyprexa, all at issue here.

**Q. ENDO**

299. As set forth in detail at Exhibit A, the City spent over \$2.6 million on Endo drugs in 2002 alone. The specific drugs paid for by the City and for which the City seeks relief include those set forth in Exhibit A hereto.

300. The City alleges an intentionally false and misleading AWP for each Endo drug listed on Exhibit A.

301. Although Endo manufactured certain generic or multi-source drugs, the City's payments were at all times based on AWP pursuant to N.Y. Soc. Serv. L. § 367-a(9).

302. Exhibit B sets forth the City's preliminary estimate of the extent of its overcharge on those Endo drugs for which it paid the greatest amount in 2002.

303. As an example, in 2002 alone, the City spent \$2,074,073 on Endo's Lidoderm. The City's most popular dosage of Lidoderm was the 5% concentration. The City estimates it was overcharged at least 21% per 5% concentration dosage as a result of Endo's false AWPs. This translates into an average overcharge of at least \$0.91 per dosage. (*See Exhibit B*).

**R. ETHEX**

304. As set forth in detail at Exhibit A, the City spent over \$300,000 on Ethex drugs in 2002 alone. The specific drugs paid for by the City and for which the City seeks relief are set forth set forth in Exhibit A hereto.

305. Exhibit A sets forth the allegedly intentionally false and misleading AWP that Ethex reported or caused to be reported for every dosage of every Ethex drug for which the City paid.

306. Although Ethex manufactured certain generic or multi-source drugs, the City's payments were at all times based on AWP pursuant to N.Y. Soc. Serv. L. § 367-a(9).

307. Exhibit B sets forth the City's preliminary estimate of the extent of its overcharge on those Ethex drugs for which it paid the greatest amount in 2002.

308. As an example, in 2002 alone, the City spent over \$172,000 on Ethex's Naproxen. The City's most popular dosage of Naproxen was the 500 mg tablet. The City estimates it was overcharged at least 80% per 500mg dosage as a result of Ethex's false AWPs. This translates into an average overcharge of at least \$0.94 per dosage. (See Exhibit B).

309. Ethex is among the pharmaceutical companies referred to above now under investigation by the House Committee of Energy and Commerce for possible improper pricing practices and failures to comply with Best Price Rebate requirements.

310. In connection with the wrongful conduct described herein, Ethex has been sued by the Massachusetts Attorney General.

#### **S. THE FOREST GROUP**

311. As set forth in detail at Exhibit A, the City spent over \$2.7 million on Forest Group (Forest and Forest Pharm) drugs in 2002 alone. The specific drugs paid for by the City and for which the City seeks relief include those set forth set forth in Exhibit A hereto.

312. The City alleges an intentionally false and misleading AWP for each drug listed on Exhibit A.

313. Exhibit B sets forth the City's preliminary estimate of the extent of its overcharge on those Forest Group drugs for which it paid the greatest amount.

314. As an example, in 2002 alone, the City spent over \$2.7 million on Forest Pharm's Celexa. The City's most popular dosage of Celexa was the 20 mg tablet. The City estimates it was overcharged at least 19% per 20 mg dosage as a result of Forest Pharm's

false AWPs. This translates into an average overcharge of at least \$0.39 per dosage. (See Exhibit B).

315. Forest Pharm now is the subject of an investigation referred to above led by Senators Grassley and Baucus of the Senate Finance Committee regarding whether it is abusing the Nominal Price Exception to the Best Price reporting requirements.

316. Forest now is the subject of an investigation referred to above by the Office of the Inspector General of the Office of Personnel Management concerning marketing practices for mental health drugs.

#### T. THE FUJISAWA GROUP

317. As set forth in detail at Exhibit A, the City spent over \$2.3 million on Fujisawa Group (Fujisawa and Fujisawa USA) drugs in 2002 alone. The specific drugs paid for by the City and for which the City seeks relief include those set forth in Exhibit A hereto.

318. The City alleges an intentionally false and misleading AWP for each Fujisawa Group drug listed on Exhibit A.

319. Exhibit B sets forth the City's preliminary estimate of the extent of its overcharge on those Fujisawa Group drugs for which it paid the greatest amount.

320. As an example, in 2002 alone, the City spent over \$435,000 on Fujisawa's Protopic. The City's most popular dosage of Protopic was the Protopic Ointment 0.1%. The City estimates it was overcharged at least 21% as a result of Fujisawa Group's false AWPs. This translates into an average overcharge of at least \$11.96 per dosage. (See Exhibit B).

321. In connection with the wrongful conduct described herein, Fujisawa Group has been investigated by at least the United States Department of Justice, the Office of

Inspector General of the Department of Health and Human Services, the Attorneys General for the State of Montana, Texas and California. The publicly available results of these investigations confirm Fujisawa's routine practice of reporting false and inflated wholesale price information and non-compliance with rebate obligations.

**U. GENZYME**

322. As set forth in detail at Exhibit A, the City spent over \$2.3 million on Genzyme drugs in 2002 alone. The specific drugs paid for by the City and for which the City seeks relief include those set forth set forth in Exhibit A hereto.

323. The City alleges an intentionally false and misleading AWP for each Genzyme drug listed on Exhibit A.

324. Exhibit B sets forth the City's preliminary estimate of the extent of its overcharge on those Genzyme drugs for which it paid the greatest amount in 2002.

325. As an example, in 2002 alone, the City spent \$1.5 million on Genzyme's Renagel. The City's most popular dosage of Renagel was the 800 mg tablet. The City estimates it was overcharged at least 17% per 800 mg dosage as a result of Genzyme's false AWPs. This translates into an average overcharge of at least \$0.18 per dosage. (See Exhibit B).

**V. GILEAD**

326. As set forth **in** detail at Exhibit A, the City spent over \$3.5 million on Gilead drugs in 2002 alone. The specific drugs paid for by the City and for which the City seeks relief include those set forth set forth in Exhibit A hereto.

327. The City alleges an intentionally false and misleading AWP for each Gilead drug listed on Exhibit A.

328. Exhibit B sets forth the City's preliminary estimate of the extent of its overcharge on those Gilead drugs for which it paid the greatest amount in 2002.

329. As an example, in 2002 alone, the City spent \$785,566 on Gilead's Viread. The City's most popular dosage of Viread was the 300 mg tablet. The City estimates it was overcharged at least 22% per 300 mg dosage as a result of Gilead's false AWPs. This translates into an average overcharge of at least \$2.67 per dosage. (*See Exhibit B*).

## **W. THE GSK GROUP**

330. As set forth in detail at Exhibit A, the City spent over \$71.5 million on GSK Group (GSK, SmithKline, Cerenex) drugs in 2002 alone. The specific drugs paid for by the City and for which the City seeks relief include those set forth set forth in Exhibit A hereto.

331. The City alleges an intentionally false and misleading AWP for each GSK Group drug listed on Exhibit A.

332. Exhibit B sets forth the City's preliminary estimate of the extent of its overcharge on those GSK Group drugs for which it paid the greatest amount in 2002.

333. As an example, in 2002 alone, the City spent over \$12 million on GSK's Combivir tablet. The City estimates it was overcharged at least 25% per dosage as a result of GSK's false AWPs. This translates into an average overcharge of at least \$2.45 per dosage. (*See Exhibit B*).

334. In connection with the wrongful conduct described herein, GSK Group has been investigated by the United States Department of Justice, the Office of Inspector General of the Department of Health and Human Services, the Attorneys General for the States of California, Colorado, Nevada, New York, Pennsylvania, Texas and Wisconsin.

335. The publicly available results of these investigations confirm GSK Group's routine practice of reporting false and inflated wholesale price information and non-compliance with rebate obligations. For example, GSK Group recently agreed to pay in excess of \$87 million to settle federal False Claims Act allegations that GSK Group repackaged and privately labeled Paxil, an antidepressant and Flonase, a nasal spray for Kaiser at discounted prices, but failed to report these lower prices as "best prices" to the government.

336. On April 13, 2003, SmithKline Beecham Corporation, d/b/a/ GlaxoSmithKline entered into a Corporate Integrity Agreement ("CIA") with the Office of Inspector General ("OIG") of the United States Department of Health and Human Services "to promote compliance" "with the statutes, regulations and written directives of Medicare, Medicaid and all other federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)" ("Federal Health Care Program Requirements"). Contemporaneously GSK entered into a Settlement Agreement with the United States and various states.

337. Persons covered by the "CIA" include all employees of the U.S. pharmaceuticals division of GSK responsible for the, *inter alia*, "reporting of pricing information for any products that are reimbursed by federal health care programs, including under the Medicaid Drug Rebate program, codified at 42. U.S.C. § 1396r-8" and "obligations related to government contracts, including the agreements entered with the Department of Health and Human Services under the Medicaid Drug Rebate program and the Drug Pricing program under the Public Health Service (PHS) Act, 42 U.S.C. § 256."

338. In addition to promising compliance with federal health care program requirements, the CIA requires GSK to establish a written code of conduct to be agreed to by each covered person that confirms GSK's "commitment to full compliance with

all federal health care program requirements, including its commitment to comply with all government contracting requirements and to market and sell its Government Reimbursed Products in accordance with federal health care program requirements.”

339. The CIA requires further that GSK implement policies and procedures that address:

- (a) The code of conduct described above as well as;
- (b) The methods for gathering, calculating, verifying and reporting the data and information reported to the Centers for Medicare and Medicaid Services (“CMS”) and/or the state Medicaid programs in connection with the Medicaid Drug Rebate program;
- (c) Promotional practices that conform with all applicable federal health care program requirements, including the Medicaid Drug Rebate program and the Federal anti-kickback statute, codified at 42. U.S.C. § 1302a-7b; and
- (d) The requirements of all government contracts, including those under the Medicaid Drug Pricing program.

340. The CIA contemplates monetary penalties for non-compliance, and the retention of an independent review organization, (“IRO”). The IRO performs two types of review: (1) a systems review of GSK’s systems, processes, policies and practices relating to the Medicaid Drug Rebate program (“Medicaid Rebate Systems Review”) and (2) a review of specific contract price transactions to determine whether those transactions were considered for purposes of determining Best Price in accordance with GSK’s policies and procedures and Medicaid Drug Rebate program requirements.

341. CIA notwithstanding, GSK’s wrongful price reporting continues. GSK is among the pharmaceutical companies now under investigation by the House

Committee of Energy and Commerce for possible improper pricing practices and failures to comply with Best Price Rebate requirements.

342. GSK Group also is the subject of the investigation referred to above led by Senators Grassley and Baucus of the Senate Finance Committee regarding whether it is abusing the Nominal Price Exception to the Best Price reporting requirements.

#### X. THE HOFFMAN-LAROCHE GROUP

343. As set forth in detail at Exhibit A, the City spent over \$4.4 million on Hoffman-LaRoche Group (Hoffman-LaRoche and Roche) drugs in 2002 alone. The specific drugs paid for by the City and for which the City seeks relief include those set forth set forth in Exhibit A hereto.

344. The City alleges an intentionally false and misleading AWP for each drug listed on Exhibit A.

345. Exhibit B sets forth the City's preliminary estimate of the extent of its overcharge on those Hoffman La-Roche Group drugs for which it paid the greatest amount in 2002.

346. As an example, in 2002 alone, the City spent over \$456,000 on Hoffman-LaRoche's Inverase. The City's most popular dosage of Inverase was the 200 mg capsule. The City estimates it was overcharged at least 23% per 200 mg dosage as a result of Hoffman-LaRoche Group's false AWPs. This translates into an average overcharge of at least \$0.50 per dosage. (See Exhibit B).

347. Hoffman-LaRoche is among the pharmaceutical companies referred to above now under investigation by the House Committee of Energy and Commerce for

possible improper pricing practices and failures to comply with Best Price Rebate requirements.

348. Hoffman-LaRoche also is the subject of the investigation referred to above led by Senators Grassley and Baucus of the Senate Finance Committee regarding whether it is abusing the Nominal Price Exception to the Best Price reporting requirements.

#### **Y. THE IVAX GROUP**

349. As set forth in detail at Exhibit A, the City spent over \$3.9 million on Ivax Group (Ivax and Ivax Pharm) drugs in 2002 alone. The specific drugs paid for by the City and for which the City seeks relief include those set forth set forth in Exhibit A hereto.

350. The City alleges an intentionally false and misleading AWP for each Ivax Group drug listed on Exhibit A.

351. Although Ivax Group manufactured certain generic or multi-source drugs, the City's payments were still based on AWP pursuant to N.Y. Soc. Serv. L. § 367-a(9).

352. Certain Ivax Group drugs listed in Exhibit A were reimbursed at certain times based on the FUL (See Exhibit C) but, as alleged herein, even the FUL is based on an intentionally false and inflated AWP.

353. Exhibit B sets forth the City's preliminary estimate of the extent of its overcharge on those Ivax Group drugs for which it paid the greatest amount in 2002.

354. As an example, in 2002 alone, the City spent over \$21,000 on Ivax Group's Baclofen. The City's most popular dosage of Baclofen was the tablet 10 mg, for which there was no FUL in 2002. The City estimates it was overcharged at least 43% per 10 mg dosage as a result of Ivax Group's false AWPs. This translates into an average overcharge of at least \$0.14 per dosage. (See Exhibit B).

355. Ivax Group is among the pharmaceutical companies referred to above now under investigation by the House Committee of Energy and Commerce for possible improper pricing practices and failures to comply with Best Price Rebate requirements.

356. In connection with the wrongful conduct described herein, Ivax has been investigated by at least the Commonwealth of Massachusetts.

**Z. JOHNSON & JOHNSON GROUP**

357. As set forth in detail at Exhibit A, the City spent over \$40.9 million on J&J Group (J&J, Janssen, Ortho Biotech, Ortho-McNeil, McNeil) drugs in 2002 alone. The specific drugs paid for by the City and for which the City seeks relief include those set forth set forth in Exhibit A hereto.

358. The City alleges an intentionally false and misleading AWP for each J&J Group drug listed on Exhibit A.

359. Exhibit B sets forth the City's preliminary estimate of the extent of its overcharge on those J&J drugs for which it paid the greatest amount in 2002.

360. As an example, in 2002 alone, the City spent over \$10.7 million on Ortho Biotech's Procrit. The City's most popular dosage of Procrit was the vial 40,000 u/ml. The City estimates it was overcharged at least 27% per vial 40,000 u/ml dosage as a result of Ortho Biotech's false AWPs. This translates into an average overcharge of at least \$128.02 per dosage. (See Exhibit B).

361. The City spent over \$1.5 million on Ortho-McNeil's Levaquin. The City's most popular dosage was the 500 mg tablet. The City estimates it was overcharged at least 21% per 500 mg tablet dosage as a result of Ortho Mc-Neil's false AWPs. This translates into an average overcharge of at least \$1.79 per dosage.